

plans that it offers, an organization must—

(i) Maintain a health information system that collects, analyzes, and integrates the data necessary to implement its quality assessment and performance improvement program;

(ii) Ensure that the information it receives from providers of services is reliable and complete; and

(iii) Make all collected information available to HCFA.

(2) *Program review.* For each plan, there must be in effect a process for formal evaluation, at least annually, of the impact and effectiveness of its quality assessment and performance improvement program.

#### § 422.154 External review.

(a) *Basic rule.* Except as provided in paragraph (c) of this section, each M+C organization must, for each M+C plan it operates, have an agreement with an independent quality review and improvement organization (review organization) approved by HCFA to perform functions of the type described in part 466 of this chapter.

(b) *Terms of the agreement.* The agreement must be consistent with HCFA guidelines and include the following provisions:

(1) Require that the organization—

(i) Allocate adequate space for use of the review organization whenever it is conducting review activities; and

(ii) Provide all pertinent data, including patient care data, at the time the review organization needs the data to carry out the reviews and make its determinations.

(2) Except in the case of complaints about quality, exclude review activities that HCFA determines would duplicate review activities conducted as part of an accreditation process or as part of HCFA monitoring.

(c) *Exceptions.* The requirement of paragraph (a) of this section does not apply for an M+C private fee-for-service plan or a non-network M+C MSA plan if the organization does not carry out utilization review with respect to the plan.

#### § 422.156 Compliance deemed on the basis of accreditation.

(a) *General rule.* An M+C organization may be deemed to meet any of the requirements of paragraph (b) of this section if—

(1) The M+C organization is fully accredited (and periodically reaccredited) by a private, national accreditation organization approved by HCFA; and

(2) The accreditation organization used the standards approved by HCFA for the purposes of assessing the M+C organization's compliance with Medicare requirements.

(b) *Deeming requirements.* The following requirements are deemable:

(1) The quality assessment and performance improvement requirements of § 422.152.

(2) The confidentiality and accuracy of enrollee records requirements of § 422.118.

(c) *Effective date of deemed status.* The date on which the organization is deemed to meet the applicable requirements is the later of the following:

(1) The date on which the accreditation organization is approved by HCFA.

(2) The date the M+C organization is accredited by the accreditation organization.

(d) *Obligations of deemed M+C organizations.* An M+C organization deemed to meet Medicare requirements must—

(1) Submit to surveys by HCFA to validate its accreditation organization's accreditation process; and

(2) Authorize its accreditation organization to release to HCFA a copy of its most recent accreditation survey, together with any survey-related information that HCFA may require (including corrective action plans and summaries of unmet HCFA requirements).

(e) *Removal of deemed status.* HCFA removes part or all of an M+C organization's deemed status for any of the following reasons:

(1) HCFA determines, on the basis of its own survey or the results of the accreditation survey, that the M+C organization does not meet the Medicare requirements for which deemed status was granted.

(2) HCFA withdraws its approval of the accreditation organization that accredited the M+C organization.

(3) The M+C organization fails to meet the requirements of paragraph (d) of this section.

(f) *Enforcement authority.* HCFA retains the authority to initiate enforcement action against any M+C organization that it determines, on the basis of its own survey or the results of an accreditation survey, no longer meets the Medicare requirements for which deemed status was granted.

**§ 422.157 Accreditation organizations.**

(a) *Conditions for approval.* HCFA may approve an accreditation organization with respect to a given standard under this part if it meets the following conditions:

(1) In accrediting M+C organizations, it applies and enforces standards that are at least as stringent as Medicare requirements with respect to the standard or standards in question.

(2) It complies with the application and reapplication procedures set forth in § 422.158.

(3) It is not controlled, as defined in § 413.17 of this chapter, by the entities it accredits.

(b) *Notice and comment—(1) Proposed notice.* HCFA publishes a proposed notice in the FEDERAL REGISTER whenever it is considering granting an accreditation organization's application for approval. The notice—

(i) Specifies the basis for granting approval;

(ii) Describes how the accreditation organization's accreditation program meets or exceeds all of the Medicare requirements for which HCFA would deem compliance on the basis of the organization's accreditation; and

(iii) Provides opportunity for public comment.

(2) *Final notice.* (i) After reviewing public comments, HCFA publishes a final FEDERAL REGISTER notice indicating whether it has granted the accreditation organization's request for approval.

(ii) If HCFA grants the request, the final notice specifies the effective date and the term of the approval, which may not exceed 6 years.

(c) *Ongoing responsibilities of an approved accreditation organization.* An accreditation organization approved by

HCFA must undertake the following activities on an ongoing basis:

(1) Provide to HCFA in written form and on a monthly basis all of the following:

(i) Copies of all accreditation surveys, together with any survey-related information that HCFA may require (including corrective action plans and summaries of unmet HCFA requirements).

(ii) Notice of all accreditation decisions.

(iii) Notice of all complaints related to deemed M+C organizations.

(iv) Information about any M+C organization against which the accrediting organization has taken remedial or adverse action, including revocation, withdrawal or revision of the M+C organization's accreditation. (The accreditation organization must provide this information within 30 days of taking the remedial or adverse action.)

(v) Notice of any proposed changes in its accreditation standards or requirements or survey process. If the organization implements the changes before or without HCFA approval, HCFA may withdraw its approval of the accreditation organization.

(2) Within 30 days of a change in HCFA requirements, submit to HCFA—

(i) An acknowledgment of HCFA's notification of the change;

(ii) A revised cross-walk reflecting the new requirements; and

(iii) An explanation of how the accreditation organization plans to alter its standards to conform to HCFA's new requirements, within the timeframes specified in the notification of change it receives from HCFA.

(3) Permit its surveyors to serve as witnesses if HCFA takes an adverse action based on accreditation findings.

(4) Within 3 days of identifying, in an accredited M+C organization, a deficiency that poses immediate jeopardy to the organization's enrollees or to the general public, give HCFA written notice of the deficiency.

(5) Within 10 days of HCFA's notice of withdrawal of approval, give written notice of the withdrawal to all accredited M+C organizations.

(d) *Continuing Federal oversight of approved accreditation organizations.* This paragraph establishes specific criteria